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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,887	10/10/2001	Yoshinao Nagashima	214089US0CONT	4455
22850	7590	02/14/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MITCHELL, GREGORY W	
		ART UNIT	PAPER NUMBER	
		1617		

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/972,887	NAGASHIMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Gregory W Mitchell	1617	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 12 October 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-5,8,12-14 and 20-44 is/are pending in the application.  
4a) Of the above claim(s) 20 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-5,8,12-14 and 21-44 is/are rejected.

7)  Claim(s) 8 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09/28/04.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

## DETAILED ACTION

This Office Action is in response to the remarks and amendments filed October 12, 2004. Claims 21-44 have been added. Claims 1-4, 8, 13, 14, and 20 have been amended. Claims 6, 7, 9-11, and 15-19 have been cancelled. Claims 1-5, 8, 12-14, and 20-44 are pending. Claim 20 has been withdrawn from consideration. Claims 1-5, 8, 12-14, and 21-44 are examined herein.

The rejections of the Office Action dated July 28, 2003 are hereby withdrawn. The following rejections now apply.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention:

Claims 1-5, 8, 12-14, and 21-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This is a **NEW MATTER** rejection. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no disclosure in the application as originally filed for claiming, broadly, of a terpene alcohol. The application as originally filed is drawn only to a sesquiterpene alcohol.

***Claim Objections***

Claim 8 is objected to because of the following informalities: it depends from a cancelled claim. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 22, 32, 33, 43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "normal" in claims 21, 22, 32, 33, 43 and 45 is a relative term which renders the claim indefinite. The term "normal" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Therefore, it is unclear what level of odor the composition may have in order to meet the invention as instantly claimed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 21-25, 32-36, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binet et al. (*Therapie*, 27(5), 893-905, relying on a verbal translation) in view of Albaugh (USPN 5095015).

Binet et al. teaches the treatment of various disorders, such as sleep disorders, mood disorders, convulsions, stress, etc. with alcohol terpenes (pp 893, 903-904). Farnesol is specifically disclosed for use in such treatments (p 893). The terpene alcohols are taught to be administered either orally or via injection (pp 897, 899). Binet et al. lacks a specific teaching of administration by inhalation.

Albaugh teaches that anxiety, sleep disorders and seizure disorders may be treated by administering pharmaceutical compositions orally, parenterally or by inhalation (Abstract, col. 11, lines 28-47).

It would have been obvious to one of ordinary skill in the art to treat sleep disorders via the inhalation of farnesol because (1) Binet et al. and Albaugh both teach the treatment of sleep disorders; (2) Binet et al. teaches that farnesol may be used for the treatment of sleep disorders; (3) Binet et al. and Albaugh both teach that the treatment of sleep disorders may be achieved by administering active agents either orally or by some parenteral means (injection); and (4) Albaugh further teaches that the administration of pharmaceutical agents suitable for the treatment of sleep disorders may be administered via inhalation. One would have been motivated to administer the farnesol via inhalation because of an expectation of success in treating sleep disorders, as taught by Binet et al.

It is noted that the administration of the farnesol to a patient suffering from a sleep disorder will obviously increase the ECG R-R interval, decrease the systolic blood pressure and decrease the diastolic blood pressure in the patient so treated because the administration of the same composition to the same population will, obviously, treat said patient by the same means whether or not those means are disclosed by the prior art.

It is also noted that it would have been obvious to one of ordinary skill in the art to administer the farnesol composition in the concentrations claimed in claims 28 and 39 because where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is respectfully pointed out that a composition with an odor below a detectable threshold, and the limitations of claims 21, 22, 32, 33, 43 and 45, are rendered obvious because the claims do not cite any further structural limitation on the composition claimed to be useful for the regulation of autonomic nerve activity. A composition and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Claims 4, 5, 26, 27, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binet et al. and Albaugh as applied to claims 1-3, 21-25, 32-36, and 39 above, and further in view of each of Gerard (FR 2697133, relying on the abstract), Alburn et al. (USPN 3632782) and Nonomura et al. (EP 1031348).

Binet et al. and Albaugh apply as disclosed above. The references lack a teaching of the specific terpene alcohol, cedrol.

Gerard, Alburn et al., and Nonomura et al. teach that farnesol and cedrol are interchangeable terpene alcohols in various physiological applications.

It would have been obvious to one of ordinary skill in the art to replace the farnesol of Binet et al. with cedrol because (1) Binet et al. teaches terpene alcohols in general; (2) cedrol is a terpene alcohol; and (3) Gerard, Alburn et al. and Nonomura et al. teach that farnesol and cedrol are interchangeable as terpene alcohols in physiological applications. One would have been motivated to utilize cedrol because of an expectation of success in treating sleep disorders with a terpene alcohol, as taught by Binet et al.

It is noted that Binet et al. teaches a treatment with the terpene alcohol itself. Accordingly, it would have been obvious to one of ordinary skill in the art to utilize a terpene alcohol in pure form for the treatment of sleep disorders. It is also noted that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claims 13, 14, 30, 31, 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binet et al. and Albaugh as applied to claims 1-3, 21-25, 32-36, and 39 above, and further in view of Liu et al. (USPN 5195514).

Binet et al. and Albaugh apply as disclosed above. The references lack a teaching of the specifically claimed method of inhalation.

Liu et al. teaches a medicinal vaporizer which produces steam and has a heating element (Abstract; col. 1, lines 56-65). It is taught that it is known in the art to mix the water to be humidified with medication so that the vapor form may be inhaled (col. 1, lines 12-17). It is also taught that it is known in the art to administer the medicinal vapor to one person at a time via the use of a mask or to entire rooms so that multiple people may breath the medicated vapor (col. 1, lines 18-49).

It would have been obvious to one of ordinary skill in the art to administer the farnesol composition of Binet et al. and Albaugh by using a medicinal vaporizer as instantly claimed because (1) Binet et al. teaches that farnesol is a medicinal composition useful for the treatment of sleep disorders; (2) Albaugh teaches that medicines useful for treating sleep disorders may be administered via inhalation, generally; and (3) Liu et al. teaches that the inhalation of medicines may be achieved in vapor form via the use of humidifiers. One would have been motivated to administer a farnesol composition in a method as instantly claimed because of an expectation of success in administering the composition to treat sleep disorders, as taught by Binet et al.

#### ***Response to Arguments/Amendments***

Applicant's arguments with respect to claims 1-8 and 12-14 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm



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